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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,176

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Yuuichi Murayama

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EXAMINER

JAVANMARD, SAHAR

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

04/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/520,176

**Applicant(s)**

MURAYAMA ET AL.

**Examiner**

SAHAR JAVANMARD

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 02/02/09.

Claim(s) 1-9 and 13-19 are pending and are examined herein.

### ***Response to Arguments***

Applicant's arguments with respect to the 103(a) rejection of claims 1-9 and 13-19 as being unpatentable over Richardson in view of Gordon (WO 00/64420) has been fully considered but is not persuasive.

Applicant argues that "neither of the references, either alone, or in the proposed combination, teaches or suggests the presently claimed methods of suppressing the proliferation of abnormal prion proteins through the claimed administration of certain amino acids to a patient who is in need of this therapy."

Examiner respectfully notes that the reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

As set forth on record, Richardson teaches a number of neurological disorders, including among many diseases, Creutzfeldt-Jacob disease (page 2, lines 22-33).

Richardson teaches that oral administration of branched amino acids can be administered in order to alleviate abnormal movement disorders. Gordon is employed to teach the presence of certain neurodegenerative diseases, in particular Creutzfeldt-Jacob disease, among others. It is the opinion of the Examiner that it would have been obvious to one of ordinary skill in the art to have employed the amino acid regimen used to treat Creutzfeldt-Jacob disease as taught by Richardson to have also employed the same regimen to treat the proliferation of prion proteins. One would expect that this would be successful, with a reasonable degree of success, because Gordon teaches that Creutzfeldt-Jacob disease, among others, is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system.

The rejection is hereby maintained for reasons of record and is restated below for Applicant's convenience.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson in view of Gordon (WO 00/64420).

Richardson teaches a method of remitting or attenuating the symptoms of abnormal movement disorders by administering a meal enriched with large neutral amino acids to patients suffering from these disorders (abstract, page 1, lines 1-3).

Richardson teaches a number of neurological disorders that are manifested by abnormal movements, including among many diseases, Creutzfeldt-Jacob disease (page 2, lines 22-33). Richardson further teaches that branched chain amino acids or aromatic acids are administered to alleviate abnormal movement disorders in particular isoleucine, leucine, and valine (page 10, lines 13-21; page 25, example 2; claims). Additionally, Richardson teaches that the branched amino acids can be administered in the form of various pharmaceutical preparations such as tablets, capsules, flavored bars, suspensions, and emulsions (page 41, lines 11-15).

Richardson does not teach neurodegenerative diseases such as scrapie, bovine spongiform encephalitis, and Gertsman-Straussler-Scheinker syndrome. Furthermore, Richardson is silent on suppressing the proliferation of abnormal prion proteins.

Gordon teaches that neurodegenerative disease Creutzfeldt-Jakob disease is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system (page 1, lines 25-30) in addition to other neurodegenerative diseases including scrapie, bovine spongiform encephalitis, and Gertsman-Straussler-Scheinker syndrome (page 23, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered a meal enriched with large neutral amino acids to patients suffering from disorders such as Creutzfeldt-Jacob disease as taught by

Richardson as a method for suppressing the proliferation of abnormal prion proteins. One would be motivated to do so because Richardson teaches treating Creutzfeldt-Jakob disease, a disease that, according to Gordon, is characterized by the appearance and accumulation of a protein-resistant form of a prion protein. Thus it would be obvious that by administering to a patient essential amino acids to treat Creutzfeldt-Jacob disease as taught by Richardson, one would also be suppressing the proliferation of prion proteins.

Furthermore, applying the same rationale, one would expect that diseases such as scrapie, bovine spongiform encephalitis, and Gertsman-Straussler-Scheinker syndrome as taught by Richardson would also be treated by administering a meal enriched with large neutral amino acids to treat the suppression of abnormal protein prion proliferation because all of these neurodegenerative diseases are characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system and it is reasonable to treat diseases that have similar characteristics with similar forms of treatment.

### ***Conclusion***

Claims 1-9 and 13-19 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617